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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,030	09/27/2001	Randy H. Ziegler	25863.00120	4807

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EXAMINER

PATTEN, PATRICIA A

ART UNIT PAPER NUMBER

1654

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/967,030

Applicant(s)

ZIEGLER, RANDY H.

Examiner

Patricia A Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 8-10 and 18-22 are pending in the application and were examined on the merits.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8 and 18 are newly rejected under 35 U.S.C. 102(e) as being anticipated by Bok et al. (US 6,096,364).

Upon further consideration, it is deemed that Bok et al. anticipated these claims because claim 1 specifically teaches the species of luteolin for lowering blood glucose; i.e., wherein R₁ is H, R₂ is OH, R₃ is H, R₄ is OH, R₅ is H, R₆ is H, R₇ is OH, R₈ is OH, R₉ is H and X is a double bond (the characteristic structure of luteolin can be found in Table II as compared to formula (I) found in col.2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-10 and 18-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bok et al. (US 6,096,364A).

Applicant's arguments were fully considered, but not found persuasive for the following reasons:

Applicant argues that Bok et al. teaches that the most effective compounds are naringin, hesperidin and rutin and argues that Bok et al. did not specifically demonstrate the effectiveness of the other compounds (p.2 – Arguments). It is noted that not only did Bok et al. teach that all of the flavonoids which fit the description characterized by formula (I) (col.2), but that the methods for using these compounds to lower blood glucose level are *particularly claimed* (see claim 1). Bok et al. need not disclose, by name, every flavonoid which meets the description of formula (I), because, as indicated previously, the ordinary artisan would have had a good expectation that all of the flavonoids which met the description of formula (I) would have lowered blood glucose levels since they are all structurally similar and especially considering Bok et al. *claimed* these particular species (although the claims do not specifically recite the name of each

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of the compounds, each compound represented by any of the combinations of R groups fall within the breath of the claim including luteolin, myricetin, dihydrokaemferol and apigenin).

Applicant argues that flavonoids are unpredictable in the art (p.3 – Arguments). Further, Applicant contends that “..the structure I taught by Bok et al. is far from a specific structure identifying a particular set of compounds. Rather this is the general three ringed backbone common to all flavones, flavonones and flavonols”. It is true that Bok et al. clearly *disclosed all of these particular embodiments in claim 1* for lowering blood glucose levels. Therefore, methods for lowering blood glucose levels with these particular compounds was known in the art at the time the Instant Invention was made.

Applicant argues that “One of skill in the art would realize the incredible variability inherent in biological effects of flavonoids and lacking any experimental evidence would not expect any particular results from the compounds listed in Table II” (p. 4- Arguments). Applicant additionally provides references which indicate that flavonoids are unpredictable in nature. While this may be true, these arguments are not convincing because the unpredictability of flavonoids is irrelevant to the fact that the Instantly claimed flavonoids were all known individually for lowering blood glucose levels. As it was pointed out in the previous Office Action, the ordinary artisan would have had been motivated to combine the ingredients for their known effects of lowering

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blood glucose level. The ordinary artisan would have had a reasonable expectation that each individual component would have this effect, *not necessarily the same exact degree of effect*. The MPEP does not require for each of the ingredients to possess the *same degree* of efficacy, on the contrary, the MPEP requires that each individual ingredient is known for the same purpose: "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Bok et al. clearly disclosed *and claimed* that all of the claimed flavonoids were useful in treating blood glucose levels. The combination of flavonoids as Instantly claimed would have been obvious to one of ordinary skill in the art, especially in light of *In re Sussman* (see previous Office Action) because each flavonoid was known individually for lowering blood glucose levels as disclosed by Bok et al.

Applicant seems to be arguing an unexpected result with regard to luteolin based upon the submitted references as well as in the Arguments (i.e., p. 6, "It would appear that the luteolin effect is more dramatic and much more rapid"). It is noted that although luteolin may have better results than other flavonoids, it was already disclosed by Bok et al. for lowering blood glucose levels and therefore is obviated by Bok et al.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (703) 308-1189. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-3906.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

12/17/03

Patricia A Patten
Examiner
Art Unit 1654



**PATRICIA PATTEN
PATENT EXAMINER**